K011395
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JUL 1 2 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

MEDTRONIC COLVIN-GALLOWAY FUTURE™ ANNULOPLASTY BAND

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and CFR 807.92.

I SUBMITTER INFORMATION

Company Name:	Medtronic Heart Valves (Medtronic)
Company Address:	8299 Central Avenue N.E. Minneapolis, MN 55432
Company Phone:	(763) 514-6600
Company Facsimile:	(763) 514-6775
Contact Person:	Charles Dowd Senior Regulatory Affairs Manager
Date Summary Prepared:	May 4, 2001

II DEVICE IDENTIFICATION

Trade/Proprietary Name:	Medtronic COLVIN-GALLOWAY FUTURE™ Annuloplasty Band [Model 638B]
21 CFR Reference:	870.3800
21 CFR Common Name:	Ring, Annuloplasty
Classification:	Class II
Panel:	CV (74) KRH

III IDENTIFICATION OF PREDICATE DEVICE

Device	Model #
Medtronic DURAN Annuloplasty Band	610B

The 510(k) also includes references to the following marketed devices:

Medtronic DURAN Annuloplasty Ring	K980534
Medtronic POSTERIOR Annuloplasty Band	K960356
Medtronic SCULPTOR Annuloplasty Ring	K905175

IV DEVICE DESCRIPTION

The Future Band is a single use, permanent, semi-flexible, implantable device intended for the repair of a patient's mitral valve. FUTURE consists of a partial band of polyester fabric covering a formed, metallic (MP35N) wire stiffener element with eyelets formed at both ends. The stiffener element is over-molded with LSR silicone. The band is marked at three locations (the two trigone locations and the center) with green-colored suture. Two trigone markers identify the eyelets in the stiffener to facilitate anchoring of the stiffener into the trigones by the surgeon with sutures. The individual band size (26, 28, 30, 32, 34, 36, and 38mm) represents the widest, straight-line distance as measured at the inside of the fabric-covered band. The band is designed for implantation in the mitral position only.

The Future Band shall be used with associated accessories that include a holder, sizers and a handle. Implantation of the band is aided with the disposable band holder. The band is released from the holder by cutting suture at two points. The Future Band sizer set will be used to assess appropriate band size. The sizers will cover all seven sizes of the Future Band and are marked with the band size and the trigone locations. The sizers are reusable and will be provided non-sterile. The reuseable annuloplasty handle, which is available in two lengths, interfaces with both the holder and the sizers.

V DESCRIPTION OF INTENDED USE

The Colvin-Galloway Future™ Annuloplasty Band is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

VI SUBSTANTIAL EQUIVALENCE

The Medtronic FUTURE Annuloplasty Band is substantially equivalent to the Medtronic DURAN Annuloplasty Band.

The FUTURE Annuloplasty Band is manufactured based on modifications to the manufacturing processes of the DURAN Annuloplasty Band. The devices contain similar raw materials and are produced using equivalent manufacturing, packaging and sterilization processes. The devices are indicated for surgical repair of mitral valves.

VII TECHNOLOGICAL CHARACTERISTICS

The FUTURE Annuloplasty Band and the DURAN Annuloplasty Band are manufactured using the same white polyester fabric, sutures and identification tag. Both products are manufactured using equivalent manufacturing, packaging and sterilization processes. The FUTURE Annuloplasty Band is semi-flexible using a metal stiffener over-molded with LSR silicone. DURAN uses a barium sulfate silicone strip as a radiopaque marker. Both the FUTURE and DURAN are manufactured for the repair of the mitral annulus.

VIII PERFORMANCE DATA

The FUTURE Annuloplasty Band is subjected to verification and validation studies. The verification/validation studies demonstrate that the modifications to the predicated device are appropriate and do not affect the intended use or performance of the device.

Manufacturing process validation is performed. The modified manufacturing processes meet all procedure requirements. Physical performance studies are conducted to verify that the device performs as intended after routine sterilization and accelerated aging cycles. Sterilization validation of the device is also completed. Based on the results of the study, the sterility assurance level (SAL) of the sterilization process is qualified at 10^{-6} sterilization level. The verification/validation studies demonstrate that the modifications to the manufacturing process are appropriate and do not affect the intended use of the product.

No changes have been made to the manufacturing or sterilization of this device to warrant new or additional biocompatibility testing of the device components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Medtronic, Inc.
c/o Mr. Charles Dowd
Senior Regulatory Affairs Manager
8299 Central Avenue NE
Minneapolis, MN 55432

Re: K011395/S001
Trade/Device Name: Medtronic COLVIN-GALLOWAY FUTURE™ Annuloplasty Band
Regulation Number: 870.3800
Regulatory Class: II
Product Code: KRH
Dated: June 11, 2001
Received: June 12, 2001

Dear Mr. Dowd:

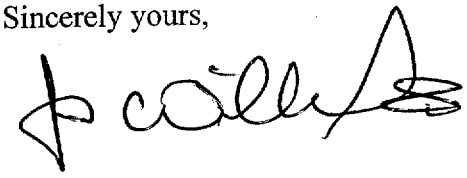
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K01 1 3 9 5

Device Name: Medtronic COLVIN-GALLOWAY FUTURE™ Annuloplasty Band [Model 638B]

Indications for Use:

The Colvin-Galloway Future™ Annuloplasty Band is indicated for the reconstruction and/or remodeling of pathological mitral valves. Valvular insufficiency and/or stenosis may be corrected by appropriate repair and annular remodeling.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
Per 21 CFR 801.109

Division of Cardiovascular & Respiratory Devices
510(k) Number K011395